Executive Summary

The Toxic Substances Control Act (TSCA) of 1977 requires the collection, analysis, and distribution to the public of large amounts of industry data. This document is a macro level baseline of the current processing executed under TSCA. Information in this document will be used in the second volume of this report, recommendations for reengineering TSCA business processes. Because the bulk of TSCA processing derives from requirements in sections 4, 5, 8, and 12, the business process reengineering effort focuses primarily on these areas. This includes processing industry submissions of Export Notices, Health and Safety Studies, and Premanufacture Notices.

In addition to documenting "as-is" processes, LMI and the Office of Pollution Prevention and Toxics (OPPT) jointly conducted a "brainstorming" session to solicit ideas in this reengineering effort. These ideas are included in the Appendix.

Most of the data used in the production of this document was gathered over the course of more than one dozen interviews with EPA personnel in OPPT and other offices of EPA during the period October through December 1997. Notable findings from this part of the study include the following:

- Processing Export Notices, from document receipt to letter generation and mailing to the country of import, frequently take longer than the 5 days allowed by law, primarily because all notices, 98% of which are Non-Confidential Business Information (NCBI), process first through the Confidential Business Information Center (CBIC).

- There is a multi-year backlog of Health and Safety studies awaiting indexing and data entry into the tracking system.

- Dozens of independent databases, applications, and modeling programs have been developed within OPPT to aid in processing Pre-Manufacture Notice (PMN) data, yet there exists no single electronic store of the PMN itself. The result is processing that is fragmented and redundant.

- CBIC processing is a paper and labor-intensive process that often delays actual analysis of the submission by two to five days. Also, the additional paper generated by the CBIC has the effect of reducing document security, running counter to the entire CBI process.

- Information management at the NCIC is so fragmented that each docket has a separate data storage file (over 100 in all) seriously limiting any data recall potential at the NCIC.

The primary conclusion drawn from these findings, and from input given by EPA personnel during interviews and the "brainstorming" session, is that electronic receipt, processing, and distribution of TSCA information can greatly improve OPPT's ability to meet the goals of TSCA. Existing, established technology and data exchange standards offer OPPT the opportunity to reengineer the entire TSCA process to one that is much quicker, cheaper, and more secure.

The key to a more effective process is creating an electronic processing architecture that includes electronic document receipt from the manufacturer, electronic routing through EPA processing, and quick, easy electronic distribution to the public. In a previous phase of this study we recommended standards, methods, and strategies for establishing an electronic partnership with industry for the purpose of TSCA submissions. The next phase of this study will identify alternatives for reengineering the processing and distribution functions.

Chapter 1
Health and Safety Baseline

TSCA sections 4, 8(d), 8(e) and FYI provide EPA with broad authority to require chemical manufacturers and processors to provide health and safety test data and study results. Health and safety submissions are formatted by the individual manufacturer or laboratory submitting the information. The length of the document can vary widely and can be up to 1,000 pages. EPA may receive 2000 submissions a year (averaging 3.5 studies per submission).

Companies may complete a voluntary health and safety cover sheet summarizing a study and mail the form along with the study to the Existing Chemicals Program of OPPT. EPA and industry jointly developed the cover-sheet as a way to index the study by allowing the manufacturer to provide summary data. The study itself is archived, currently in microfiche. All health and safety studies are scrubbed to remove any CBI from public access copies and then input into various data management systems. Studies are then forwarded to EPA scientists for technical assessment and evaluation. This process is illustrated in Figure 1-1.

ɔcess Objective

The objective of the health and safety study review process is to enable the EPA to assess the potential for harm to humans and the environment from existing chemicals that are manufactured, processed or imported into the United States. To meet that objective, the OPPT Existing Chemicals Information Program collects health and safety study data in various databases designed to perform the following functions:

- internally track all submissions;
- track and provide management statistics for certain non-confidential submissions;
- document the results of assessments and evaluations;
- provide public access to non-confidential, unpublished studies and the results of assessments and evaluations.

tailed Description of the Process

ATUTORY AUTHORITY

Under section 4, the EPA can require a manufacturer or processor to conduct testing of a chemical substance or mixture. Such testing is used to develop data otherwise unavailable with respect to the substance's potential health and environmental effects. The data are used by the EPA to determine if the chemical does or does not present an unreasonable risk of injury to health or the environment. Upon receipt of any test data which indicates that a chemical presents or will present an unreasonable risk, the EPA will, within 180 days of the date of the receipt of such data, initiate appropriate action under section 5, 6, or 7 to prevent or reduce such risk or publish a finding that such risk is not unreasonable. TSCA section 8(c) requires companies to collect allegations of significant, adverse reactions and keep records of them. Under section 8(d), the EPA can require manufacturers and processors to submit unpublished health and safety studies on TSCA-covered chemicals. Under section 8(e), firms must report immediately to EPA any time they receive information that reasonably supports a conclusion that a substance presents a substantial risk to humans or the environment.

SUBMISSION

When a company provides a submission as required under TSCA section 4, 8(d), 8(e), or FYI, it may complete a voluntary health and safety cover sheet. The form itself contains information such as:

- Basic information about the type of submission that is being provided and whether the cover sheet or submission contains CBI.
- General Information including submitter and testing laboratory (if applicable) name, company, points of contact, the report or study title and data about the chemical(s) (including CAS number, purity, and in the case of mixtures, component chemicals). The bottom of the form provides a signature and date line.
- Indexing terms that identify whether the study relates to health or the environment, the detailed study type, the subject organism, route of exposure, and vehicle.
- Additional study comments or interpretation that could assist the EPA in screening and reviewing the submission.

The study is the legal submission which is provided along with the voluntary cover sheet as well as attachments which include an abstract or summary for each study prepared by or for the submitter.

TSCA section 14 allows a company to claim certain categories of the information submitted as CBI. Generally the company must show that the information is in fact proprietary, the company has taken steps to keep the information confidential, and that substantial economic harm will result to the company should the information be disclosed.

The manufacturer then mails the package of information to EPA.

ɔcument Receipt at EPA

EPA receives health and safety submissions at the mailroom where they are forwarded to the CBIC. The CBIC opens the packages, date and time stamps them, and packs them for delivery to the document control office (DCO) for functional review. A functional expert reviews the document for basic quality control. If the document is incomplete, the company is contacted for the missing information. The DCO staff then stamps the documents as "CBI" or "NCBI" and returns the documents to the CBIC.

The CBIC processes the documents as follows:

- Management data from the submission is entered into the Confidential Business Information Tracking System (CBITS). The data entered include submission type, company name, and date of receipt.
- The original submission is archived in accordance with CBIC policy.

and FYI Submission Processing within EPA

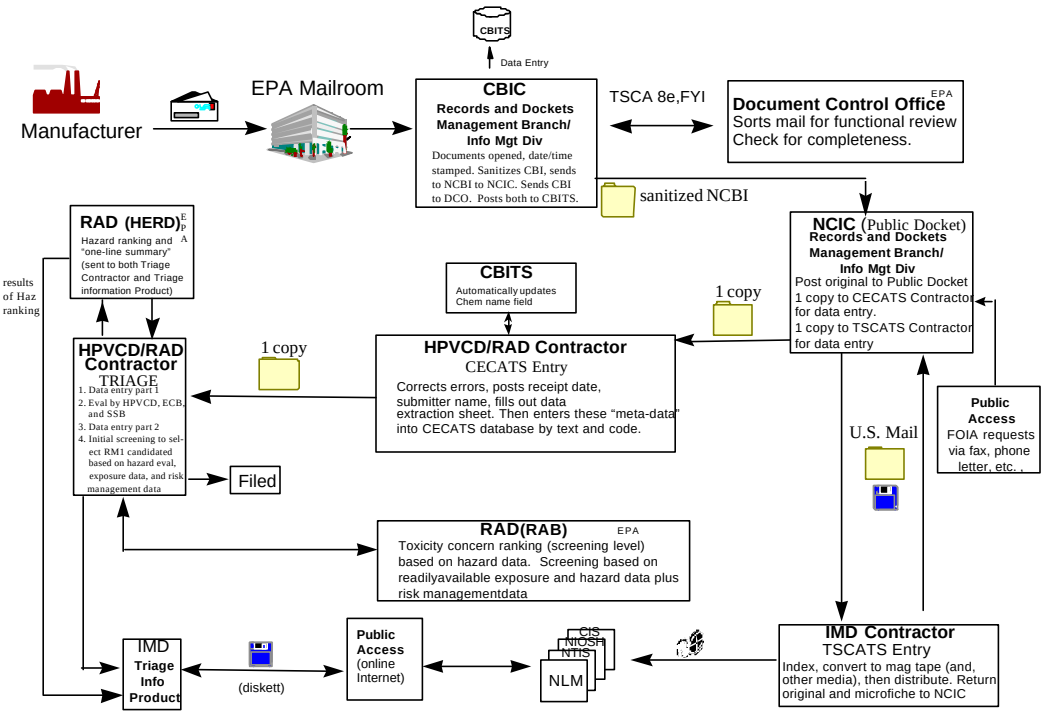
Figure 1-1 depicts the process flow for 8E and FYI submissions. Sanitized copies of the original submission are sent to the NCIC [Information Management Division (IMD) contractor] for further processing. The NCIC makes two copies and places the original in the TSCA Public Docket. The first copy is sent offsite (IMD contractor) for Toxic Substances Control Act Test Submissions database (TSCATS) data entry. The second copy is sent to Risk Assessment Division (RAD) for CSRAD[1] Existing Chemical Assessment Tracking System (CECATS) data entry [High Production Volume Chemicals Branch (HPVCB/RAD) contractor], Triage data base data entry (HPVCB/RAD contractor), as well as triage hazard evaluation and screening by HPVCB.

PURPOSE OF THE TSCATS DATABASE

The TSCATS database is used to index, convert to magnetic tape, and distribute TSCA sections 4, 8d, 8e, and FYI submissions, or for chemical effects data that are sent voluntarily.

[1] CSRAD = Chemical Screening and Risk Assessment Division

Figure 1-1. 8e and FYI Submission Data Process



INPUT TO TSCATS

The NCIC performs completeness and page sequence checks of each submission by tracking number, and mails the paper submissions to the IMD contractor that maintains the TSCATS database. The contractor generates index data for each study reported in a single submission or tracking number, writes the index data to magnetic tape, and converts the hard-copy to microfiche. The contractor produces several copies of the magnetic tapes and microfiche for government and public use of the data. The contractor provides a copy of the indexed data or a data extract to the National Library of Medicine, the National Technical Information Service, Chemical Information Systems, Inc., and the National Institute for Occupational Safety and Health. The contractor then returns the paper submission and provides a microfiche copy to the Records and Docket Management Branch which are filed in

the public docket. Microfiche is also filed in the OPPT Chemical Library, and distributed to the National Technical Information Service and Chemical Information Systems, Inc. for access by the public.

RPOSE OF THE CECATS DATABASE

The CECATS database presently tracks and provides statistics for all non-CBI 8e and FYI submissions and has historically tracked Chemical Hazard Information Profile (CHIP), Pre-CHIP and Substitute chemical documents.

UT TO CECATS

Upon receipt of the copy of an 8e or FYI submission provided by the NCIC, the HPVCD/RAD contractor dates the submission and logs it in as having been received by the HPVCD/RAD. The contractor also completes a data extraction sheet using information from the submission and adding possible cross-reference information from such sources as previous submissions, and the Chemical Abstract Service's (CAS) On-Line system. The contractor attempts the correction of typographical errors or inaccurate data at this time. The contractor then enters the following data from the extraction sheet into the CECATS database as text or with numeric codes:

- Submission number
- Submitter name
- Chemical name(s)
- CAS number(s)
- Pertinent dates to include the submitter date, OPPT receipt date, and the RAD receipt date
- Voluntary actions undertaken by the submitter
- Submission disposition
- Information types

After the entered data are reviewed for accuracy, the submission is filed until the Triage process is initiated. The CBITS database is updated as a result of corrections that may be made to fields such as the chemical name or CAS number.

RPOSE OF THE TRIAGE DATABASE

The TRIAGE database was developed to track Triage screening status and evaluations, and screening assessments by the RAD staff.

UT TO TRIAGE

HPVCD/RAD provides the submission to the contractor that maintains the TRIAGE database. The contractor enters the following initial data into TRIAGE:

- Submission number
- Chemical name
- CAS number
- Chemical use as provided by the submitter
- Study type
- Species type
- Production level (high or low)

After the contractor enters these data, the RAD staff from the HPVCB, the Existing Chemicals Branch (ECB) and the Science Support Branch (SSB) conduct Triage evaluation. The contractor then enters the results of that evaluation into the TRIAGE database. The contractor also provides the submission to the appropriate RAD staff (formerly the Health and Environmental Review Division component-HERD). RAD staff assigns a toxicological ranking of "high", "medium", or "low" to the study and prepare a short summary justifying the ranking. The RAD staff then returns the ranked study to the contractor for final TRIAGE data entry. The contractor enters the ranking and summary into TRIAGE and provides the data to the IMD to develop the Triage Information Product. The contractor will, at this time, either provide the submission to RAD for screening at a later date or file it. RAD provides feedback to the IMD on corrections to fields such as the chemical name and CAS number so that those corrections can be made to CBITS.

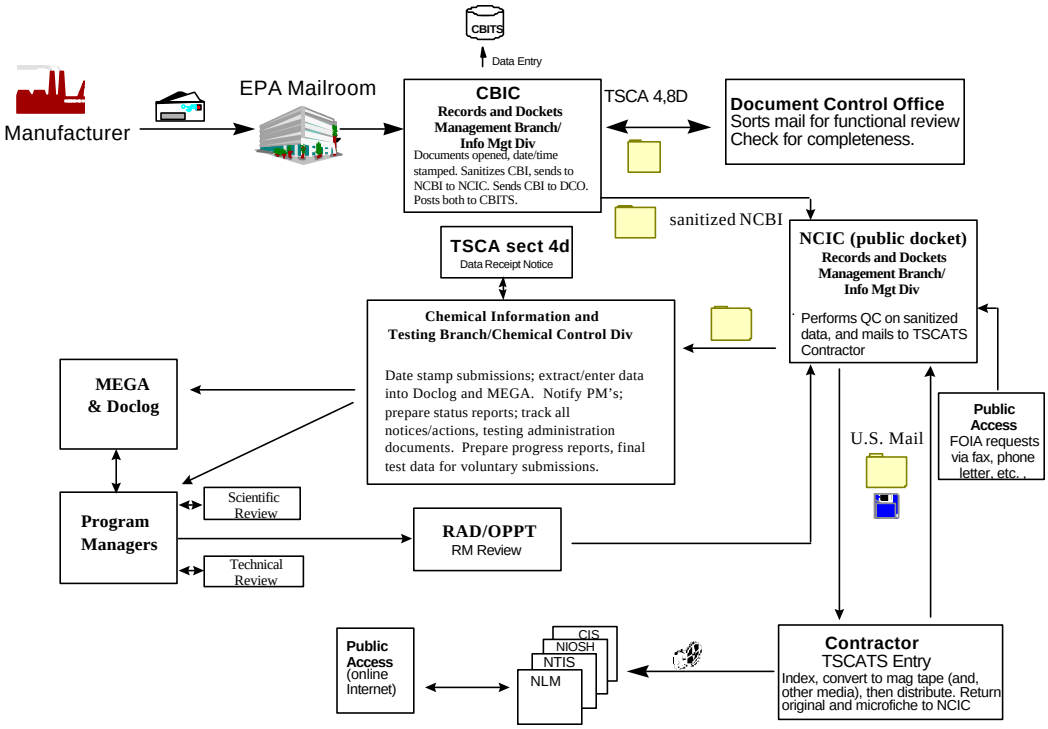
RAD's initial screening exercise to select RM1 candidates is based primarily on triage hazard evaluation, exposure data and risk management information. In addition to the submission, additional data may be reviewed during screening. The following information is determined as an outcome of the screening exercise:

- Assessment or regulatory status of the chemical
- Referrals
- Screening disposition and rationale to continue or discontinue assessment
- Statement of additional information needed to continue the assessment
- Any additional toxicity or exposure data used for the screening assessment

nd 8(d) Submission Processing within EPA

Figure 1-2 depicts the process flow for 4 and 8d submissions. Sanitized copies of the original submission are sent to the NCIC [Information Management Division (IMD) contractor] for further processing. The NCIC makes two copies and places the original in the TSCA Public Docket. The first copy is sent offsite (IMD contractor) for TSCATS data entry. The second copy is sent to the Chemical Information and Testing Branch (CITB) of the Chemical Control Division (CCD).

Figure 1-2. 4 and 8d Submission Data Process



The NCIC performs quality control on the sanitized 4 and 8(d) submissions and mails the paper submissions to the IMD contractor that maintains the TSCATS database. The functions performed by the TSCATS contractor for 4 and 8(d) submissions are the same as described for the 8e submissions above.

The CITB, upon receipt of 4 and 8(d) submissions from the NCIC, date stamps the submissions, extracts specific data from each submission and enters the data into the MEGA and Doclog databases. The CITB then notifies the Program Managers of submission receipts who initiate scientific and technical reviews. The results of the reviews are provided to RAD for risk management review. The results of the risk management review are then provided to the NCIC for retention in the public docket.

The CITB also prepares status reports, and tracks all notices/actions and testing administration documents. Finally, the CITB prepares progress reports and final test data for voluntary submissions.

ficiencies in the Process

Based on current processing, we make the following observations:

- Electronic access to and storage of health and safety data is redundant and fragmented;
- The databases and systems used for health and safety data management are mostly incompatible because of software and format dissimilarities;
- Some data are not available to the public (and other government agencies) because of system, structure, file, process, format and interface incompatibilities;
- Data that are keyed (or typed) by the manufacturer or importer must be rekeyed into multiple software applications;
- Analysis and processing of health and safety data is redundant and fragmented;
- The process is paper and labor-intensive;
- Over 1 year's backlog of health and safety submissions is queued awaiting TSCATS input.

Chapter 2 Chapter 2
Export Notice Baseline

TSCA Section 12(b) requires that foreign countries be notified whenever a material subject to other sections under TSCA is exported from the United States to that country. Specifically, the law states in paragraph (1):

> If any person exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under section 4 or 5(b), such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of the availability of the data submitted to the Administrator under such section for such substance or mixture.

In paragraph (2), the law extends this requirement to those materials with rulings or rulings pending under other sections of TSCA:

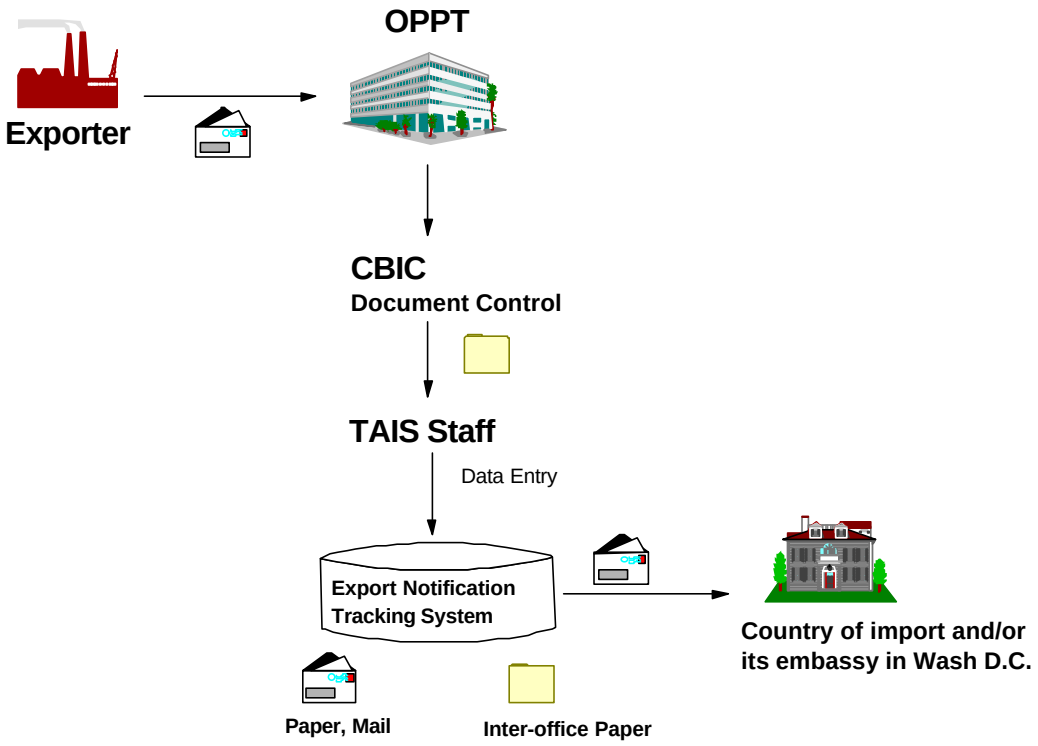
> If any person exports or intends to export to a foreign country a chemical substance or mixture for which an order has been issued under section 5 or a rule has been proposed or promulgated under section 5 or 6, or with respect to which an action is pending, or relief has been granted under section 5 or 7, such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of such rule, order, action, or relief.

Process Objective

The primary objective of TSCA 12(b) is to alert and inform countries of possible health and environmental hazards from chemical substances or mixtures that are subject to certain controls under TSCA.

In order to meet the requirement of the law, OPPT contracts to have the TSCA Assistance Information Service (TAIS) perform the duties required by the Administrator under 12(b). In summary, the TAIS staff receive letter notices from manufacturers identifying chemical substances or mixtures to be exported, the date of export, the country of import, and the applicable section from TSCA under which data has been submitted or is pending ruling or submission. The TAIS staff then enters these data into a database, generate standard letters to the embassies of the subject countries, and mail the letters along with applicable documentation. This process is illustrated in Figure 1-1.

Figure 1-1. Macro Level Export Notice Process



Detailed Description of the Process

A manufacturer or exporter who intends to export a product under which reporting is required under final sections 4 or 5, or pending under sections 5, 6, or 7 notifies the Administrator by sending a letter to the EPA within 7 days of contractual agreement to export or the date of actual export (whichever is sooner). Export notices are received via the mail and given to the OPPT staff for classification as containing Confidential Business Information (CBI) or not (NCBI). Under section 14(c) of TSCA, manufacturers may claim the information as confidential. OPPT estimates that 2% of export notices are declared as confidential business information (CBI), but all documents are sent to the CBI after the initial screening by OPPT.

At the CBIC, the notices are separated into “CBI” and “NCBI” and stamped accordingly. NCBI notices wait to be picked up by an export specialist on the TAIS staff. CBI notices are coded, assigned a Document Control Number (DCN), logged in, and photocopied. “Coding” means that the relevant data are identified and coded based on how the data are entered into the database. The original document is then archived in accordance with CBIC procedures, and the copy awaits pickup by an export specialist from the TAIS staff.

At the TAIS center, the NCBI notices are coded, assigned a DCN, and keyed into the Export Notification Tracking System (ENTS) database. CBI copies of notices are entered into a TAIS logbook with the following data: DCN, number of pages, and company name and address. The data from the CBI notices are then keyed into ENTS.

Standard letters are then generated for mailing to the subject country embassy and/or to an official located in the subject country. Letters are sent if it is the first notice of the calendar year to that country for chemicals regulated under sections 5 and 6, or if it is the first notice ever for chemicals regulated under section 4. The body of the letter is used to inform subject country's embassy that the chemical was or is being exported to their country and that it is regulated under the applicable section of TSCA. Letters include enclosures such as federal register notices and other information. Letters generated for notices sent as CBI include a coversheet stamped with the heading "TSCA Confidential Business Information; Does Not Contain National Security Information." Letters are then sealed and delivered to the CBIC for mailing.

Key Metrics and Components

INCOMING NOTICES

The EPA receives approximately 10,000 notices annually, about 2% of which are classified as CBI.

PROCESSING TIME

There is normally no backlog in processing at the TAIS center. From time of receipt by TAIS center personnel to data entry is typically between 1 and 5 days. Letters are generated every Friday. Total processing time, from receipt at OPPT to letter generation normally takes more than 5 business days and may occasionally take up to two to three weeks depending upon processing at the CBIC.

OUTGOING LETTERS

Approximately 1500 letters are generated to foreign government embassies every year.

DATA PROCESSING

It takes approximately 30 seconds to enter the data for one notice into ENTS, not including the coding required before data entry. Coding may take 30 seconds to a minute or more if a reference must be used to lookup the code for a chemical or country.

CBIC PROCESSING

OPPT estimates that processing CBI export notices take less than 5 minutes for each document. The fact that all notices are first routed through the CBIC, however, can occasionally result in delay of 4 or more days.

INFORMATION SYSTEMS

The Export Notification Tracking System is a Nexbase database engine (a dBase derivative). It operates in a DOS environment as a Clipper application. Data are entered into block-style entry screens. There are no other AIS's associated with this process.

DOWNSTREAM APPLICATIONS OF DATA

To the best knowledge, the data from the TSCA 12(b) process are not widely used elsewhere with OPPT or the EPA . The end users of the data are the foreign countries. Their use of the data is generally undocumented. The TAIS may receive approximately 70 inquiries a year from embassies requesting further information. Recently the TAIS staff has been furnishing reports via e-mail to the Office of Enforcement and Compliance Assurance (OECA) of those notices received after the intended date of export.

Deficiencies in the Process

Based on current processing, we make the following observations:

- Data that are keyed in once by the manufacturer have to be rekeyed at the TAIS Center.
- Processing at the CBIC and TAIS delay notice to the country such that the 5 day window defined by law may often be exceeded.
- All notices, whether CBI or NCBI, are processed through the CBIC which can be the primary source of delay. In addition, duplicate data entry occurs for CBI notices (once at CBIC and once at TAIS Center).

Chapter 3 Chapter 3
Premanufacture Notice Baseline

TSCA section 5 requires that any company planning to manufacture or import a chemical not already on the TSCA inventory to submit to EPA a notice containing information on the identity, use, production or import volume, hazards, and disposal characteristics of the material. The EPA then has 90 days to consider the notice and either drop the notice from review (allowing production or import to proceed), request additional information, or regulate the item. Under section 5 EPA may employ a "significant new use" rule, or SNUR, to control a new use of a chemical already on the TSCA inventory. Under section 6 EPA may move to prohibit production of an existing substance or control the conditions under which it is manufactured.

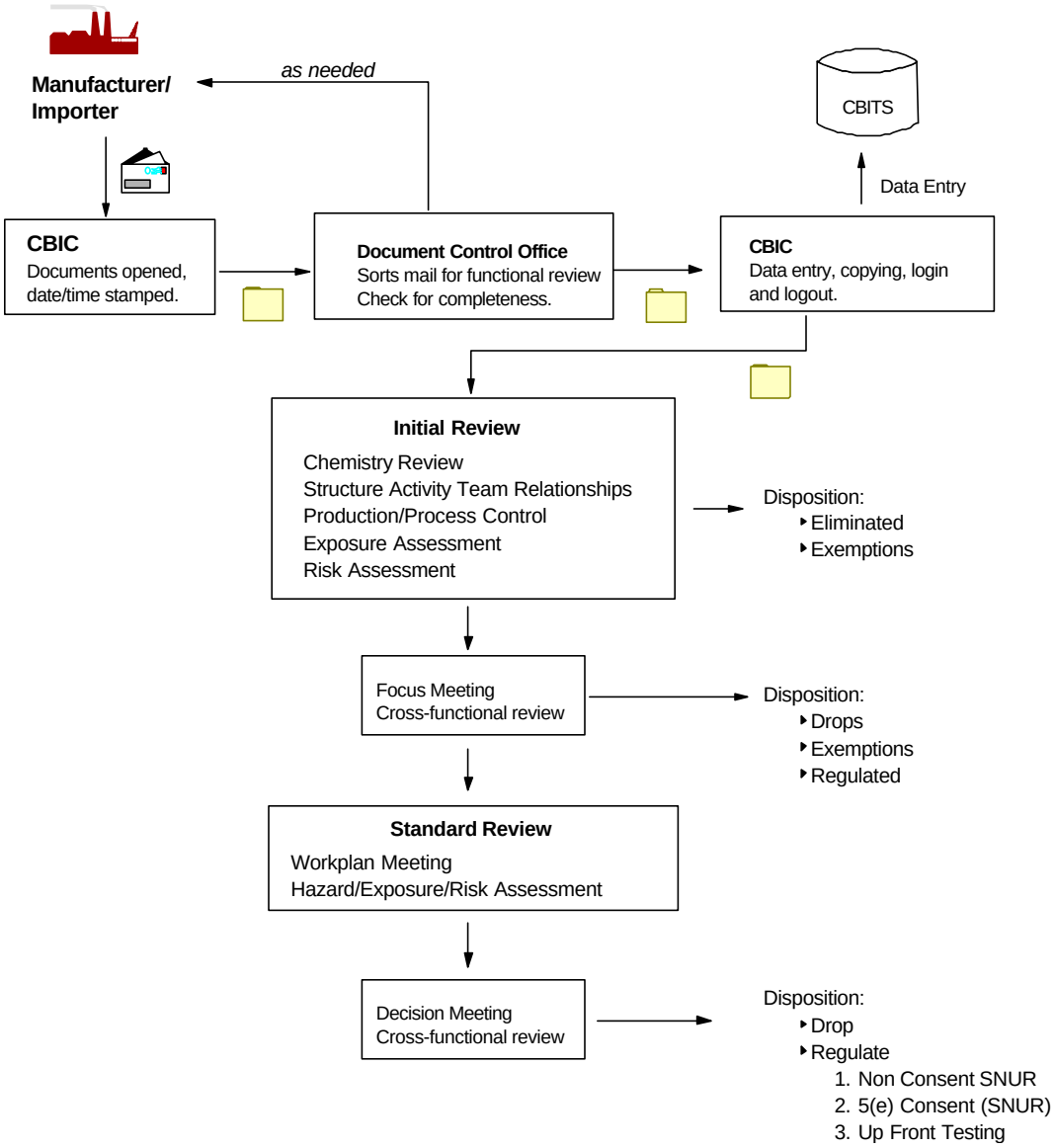
Process Objective

The primary objective of TSCA section 5 is to protect public and environmental health by ensuring that new substances[2] are not produced or imported in mass quantities until the risks associated with that substance are better understood, and, if necessary, to regulate production or import of that substance to prevent unnecessary risk to health and environment. TSCA section 14 also requires that the EPA accomplish this while being a responsible steward of proprietary business information. Secondary objectives of the process as implemented include: maintaining document control, adding to the body of knowledge used to assess new chemicals, and preventing pollution by sharing production controls information.

In order to meet the requirements and intent of the law, the New Chemicals Program of OPPT collects premanufacture notice (PMN) information from manufacturers or importers on a PMN form. In summary, companies complete the PMN form and mail it to the EPA. Supplementary information such as test data and Material Safety Data Sheets (MSDSs) may be included with the submission. The PMN form is processed for CBI and copies are distributed to various subject matter experts (SME) such as chemists, engineers, and economists. A series of review meetings and individual analysis from the SME's result in a decision to either "drop" the PMN based on a perceived low level of risk or to continue further research and review of the substance to better understand the risk level to health and environment. At approximately 90 days after receipt of the PMN, a decision is made based upon one of four possible outcomes. They are depicted in the PMN process Figure 3-1.

[2] Only for those new chemicals which are subject to TSCA (i.e., not regulated by another statute).

Figure 3-1. Macro Level View of PMN Process



Detailed Description of the Process

COMPANY SUBMISSION

A manufacturer or importer who intends to manufacture or import a new chemical substance in the United States must complete and submit to the EPA the Premanufacture Notice (or request an exemption based on low volume, low release, or test marketing purposes). Under section 5, the EPA has 90 days to make a decision regarding the commercial manufacture or import of the substance. New chemicals are those substances not already identified on the U.S. EPA TSCA inventory. The TSCA inventory is maintained by EPA with additions resulting from a PMN and corresponding Notice of Commencement or Import (NOC).

Companies may access periodically updated electronic copies of the inventory through various information outlets such as NTIS and the Chemical Abstract Services (CAS).

Once a company has determined that a substance is not currently on the TSCA inventory and is subject to PMN reporting[3], it must complete and submit a PMN, EPA Form 7710-25 (approved by the Office of Management and Budget), and remit the appropriate fee ($2,500 or $100 for qualifying small businesses). The form may be filled out by a number of the company's functional specialists (i.e., chemists, production engineers). The form itself contains information in sections such as:

- Basic information about what type of request is being made and what documentation is provided. This section also includes a certification of intentions and a signature block.
- General Information including name, company, points of contact, data about the chemical(s) (including composition, CAS number if available, molecular structure, trade names, and synonyms), production volumes, and basic commercial use.
- Human Exposure and Environmental Release information such as the location of the production site(s), a description of the production process, the number of workers exposed during production and the nature of exposure, and environmental release and disposal.
- Pollution Prevention Information, as a narrative, provided at the company's discretion.
- Attachments which may include physical/chemical properties, any health and safety studies the company may possess, MSDSs, and any other documentation the company feels may impact the EPA ruling.

TSCA section 14 allows a company to claim much of the information submitted as CBI, with the exception of health and safety data. The company will have to substantiate the claim of CBI once the company files the Notice of Commencement of Manufacture or Import (in order to add an approved PMN to the TSCA Inventory). Generally it must show that the information is in fact proprietary, that the company has taken steps to keep the information confidential, and that substantial economic harm will result to the company should the information be disclosed.

The prospective manufacturer or importer then mails the package of information to EPA. If the documentation contains CBI, the package will normally be double-

[3] Chemicals subject to reporting are those not regulated by other laws or acts such as drugs, tobacco, cosmetics, or pesticides. Other exemptions may be made for substances manufactured only for export, manufactured in low volume, or of a particular chemical nature (such as polymers).

wrapped sent via certified mail or hand delivered by a courier service. The company is then also required to submit a "sanitized" version of the document with all CBI removed.

DOCUMENT RECEIPT AT EPA

EPA receives PMNs at the mailroom where they are forwarded to the CBIC. The CBIC opens the packages, date and time stamps them, and packs them for delivery to the OPPT/IMD document control office (DCO) for functional review. At this point the "90-day clock" has started. A subject matter expert (SME) reviews the document for basic quality control. If the document is incomplete, the company is contacted for the information and the "clock" stops. The DCO staff then stamps the documents as "CBI" or "NCBI" and returns the documents to the CBIC in the basement of the building. The DCO then sends the sanitized version to the NCIC or public docket.

The CBIC processes the documents as follows:

- Management data from the submission is entered into the CBITS. The data entered include submission type, company name, chemical name, and date of receipt.
- Seven photocopies are made of the original submission and each copy is assigned a unique DCN for tracking purposes. The copies are then placed in mail boxes for each of the functional groups that review the submission within the New Chemical Program.
- The original submission is archived in accordance with CBIC policy.

PMN PROCESSING WITHIN EPA

The photocopies of the original PMN submission are sent to functional areas for analysis and entry into the ongoing review cycle. The functional areas include Chemistry Assessment, Production/Process Control Characterization, Hazard Assessment, Dose Response Assessment, Exposure Assessment, Risk Assessment, Economic Assessment, Risk Management/Regulatory Control, and Outreach.

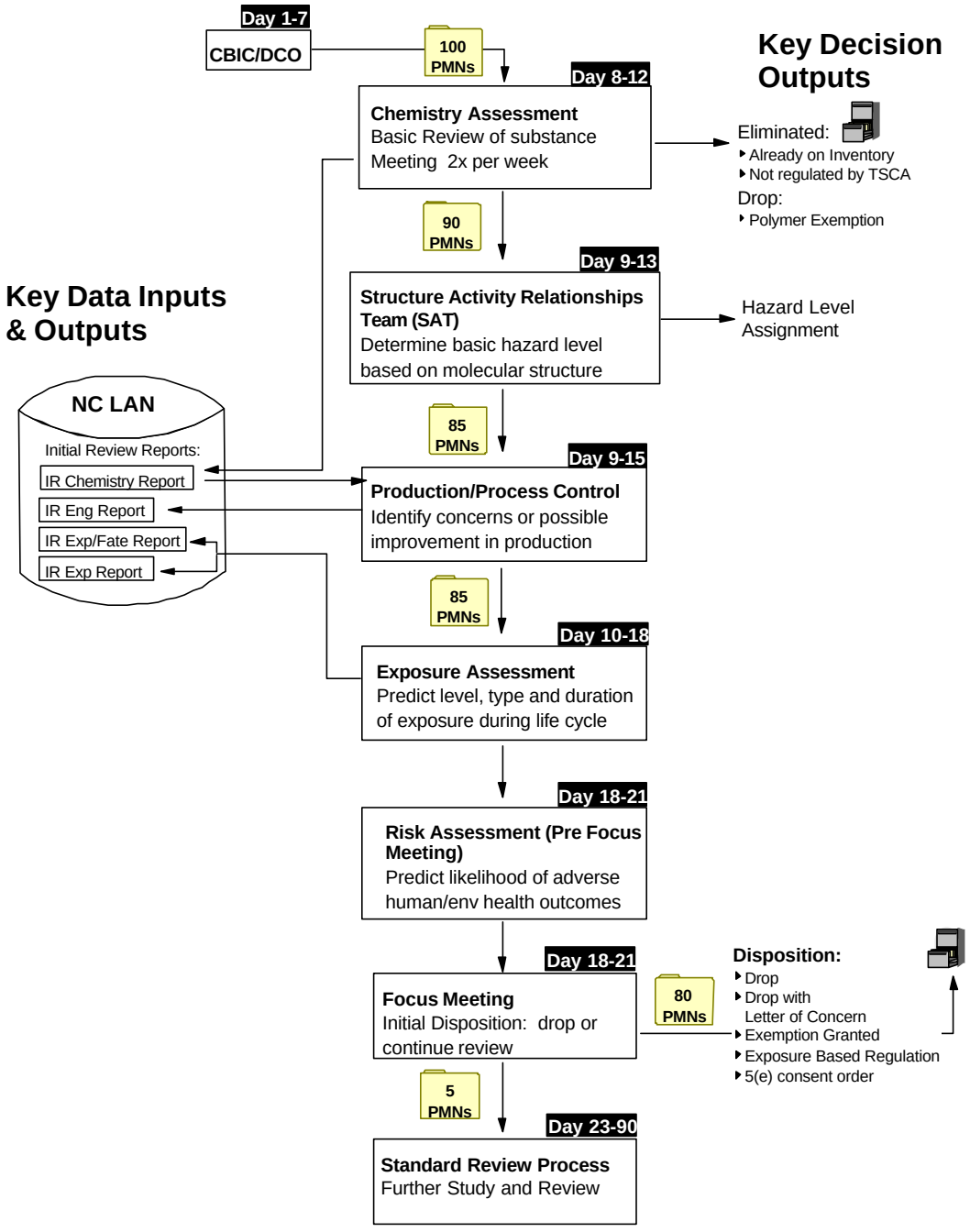
Processing of the PMN is complex and dependent upon the need to involve each functional area. It is generally serial in nature, with one group providing output in the form of a report that may be used subsequently as an input to another functional area process. The reports are stored on the New Chemicals local area network (NC LAN) sometimes referred to as the CBI LAN. Standard naming conventions and directories help individuals identify and locate the reports that are stored as word processing documents. Processing within each functional area is generally individual analysis based upon reference materials, internal and external, and modeling software. The myriad of databases and modeling programs used and consulted range from simple, in-house developed programs to sophisticated

contractor-developed applications. The platforms and networking characteristics of these programs vary widely. Many are stand-alone programs administered by individuals. Databases are often updated during the process for historical purposes. There is very little integration or connectivity.

In addition to analysis performed by each functional area, consensus is reached on item disposition through a series of meetings. The initial review culminates at the cross-functional Focus meeting which results in some type of final disposition for the majority of PMN submissions and exemption requests. Those PMNs that are not disposed of at the Focus Meeting proceed through Standard Review.

The degree to which each functional area is involved in the process is case dependent. Prior to the Focus Meeting, some functional areas do not provide input, or only provide cursory input. For those PMNs that process through the Standard Review, more detailed analyses may be required from those areas that provided initial review. Input is also then required from functional areas that participate only during Standard Review. The functional areas that normally participate in the initial review (prior to the Focus Meeting) include Chemistry Assessment, Production/Process Control Characterization, Exposure Assessment, and Risk Assessment. The information flow and processing during this initial review are illustrated in Figure 3-2.

Figure 3-2. PMN Processing Through Focus Meeting



Chemistry Assessment

The chemistry assessment reviews the PMN in order to: validate the chemical identity, predict or validate the chemical's properties, evaluate chemical reactions during processing and use, identify impurities or by-products, and identify manufacturing or processing constraints dictated by chemical properties. The

chemists may use computer programs running locally to aid in the analysis, and they may consult external data stores such as the CAS TSCA database. The output from this function includes the Initial Review Chemistry Report (IRCR), the Smart Review Report, and, when necessary, the Standard Review Chemistry Report. The report is stored electronically on the CBI LAN. A paper copy of each is sent to the CBIC for archive with the original submission.

Twice a week the Chemical Review Meeting convenes to review new PMNs. Basic questions are addressed based on available information and literature. Some PMNs are eliminated from review for reasons such as the substance already exists on the TSCA inventory or dropped because the substance may be among a broad class of low-risk substances, for example, polymers. A PMN will reach the Chemical Review meeting approximately 8-12 business days after EPA receipt.

Structure Activity Relationships Team

PMNs that are not eliminated or dropped at the Chemical Review Meeting are then reviewed by the Structure Activity Relationships Team (SAT) within two or three days. TSCA Section 5 does not require companies to perform testing on chemicals for which they submit PMNs, only that they provide test data if they are available. As a result, most submissions do not contain toxicological information necessary to determine health and environmental hazard. The SAT meeting is used to identify those analog chemicals for which hazards are known that have a structural similarity to the subject chemical. Toxicity is then predicted as a combination of environmental health hazard and human health hazard. A hazard rating of "Low/Low" (environmental/human health) will likely result in a PMN being dropped at the Focus Meeting, and these items are given less scrutiny during the processes leading up to the Focus Meeting.

Production/Process Control Characterization

This function serves to identify improvements in process controls, production changes, personal protective equipment, and technological alternatives that may result in lowered exposure and pollution during production and use. This function makes great use of the IRCR produced by the chemists. It also consults many other data sources such as the manufacturer and various handbooks and guidelines. Process modeling is done with process flow software. The Production/Process Control Characterization function uses these data and tools to complete the Initial Review Engineering Report and the Standard Review Engineering Assessment Report, stored both electronically on the CBI LAN and as paper at the CBIC with the original submission.

Exposure Assessment

Exposure Assessment identifies sources of exposure and attempts, through monitoring and predictive modeling, to assess the level and duration of chemical exposure to environment, workers, consumers, and the general public. This

function consults many other data sources during analysis (including outputs from other functional areas such as the IRCR) and uses a variety of software modeling tools to generate its assessments. This function produces reports such as the Initial Review Engineering Report, Initial Review Exposure/Fate Report, and in some cases the Standard Review Exposure/Fate Assessment Report, Test Data Exposure/Fate Review, and the Pollution Prevention Plan. These reports are stored electronically on the CBI LAN and as paper in the CBIC with the original submission.

Risk Assessment (Pre Focus Meeting)

After the reports are made available on the CBI LAN, the Risk Assessment function meets to identify ways of managing the combination of the hazard and the exposure and to predict the probability of adverse human or environmental health outcomes resulting from the manufacture or use of the subject chemical. This function receives reports from the other functions such as hazard assessment and dose response assessment. Risk assessment uses data from a variety of internal and external data repositories, both in paper and electronic format. Reports produced by risk assessment may include, when necessary, the Standard Review Risk Assessment Report, Test Data Risk Review, and the New Chemicals Exposure Limits. These reports are stored on the CBI LAN and at the CBIC.

Focus Meeting

Approximately two to three weeks after initial receipt of the PMN, the Focus Meeting group convenes to review the functional assessments and issue initial disposition. In addition to the functional reviews provided, the economic function provides an assessment of socioeconomic cost and benefit. Nearly all of the PMNs that reach the Focus Group meeting reach a definite outcome. Only five percent go on to the Standard Review and require further analysis and review at the division director level. The possible outcomes from the focus meeting for PMNs include:

- Drop. PMNs that are dropped require no further action.
- Drop with Letter of Concern based on information provided about the company's business process. Approximately 80% of PMNs are dropped or dropped with a letter of concern after the Focus Meeting.
- Exemption submissions (Test Market 45-day review, Low Volume 30-day review, and Low Release/Low Exposure 30-day review) are granted or denied based on the information provided.
- Regulate the chemical based on certain criteria:
  - the chemical falls under one of approximately 40 "categories of concern."

- Signed 5(e) consent order or non 5(e) Significant New Use Rule (SNUR).
- Ban up-front testing (BUFT) which may require the company to submit more data after an initial production or import period.
- Exposure or risk-based finding.

◆ Continue review of the chemical through the Standard Review process.

Standard Review

The five percent or so of PMN submissions that reach the Standard Review Process, after approximately 30 days, are candidates for some kind of regulation due to a lack of information, a lack of knowledge, or an apparent threat to human and environmental health. Soon after the Focus Meeting, PMNs requiring further review are discussed at a Workplan Meeting with the intention of identifying what analysis is required to make a determination. Functions such as Chemistry Assessment and Exposure Assessment may be required to provide a more in-depth study for the Standard Review. Functional areas such as Hazard Assessment and Dose Response Assessment may be required to provide initial input. At approximately day 80, a decision meeting is convened and some regulatory action is taken and the manufacturer or importer notified.

Post Review

Once a PMN reaches some disposition, the documentation is supposed to be returned to CBIC for regular destruction. PMNs that have been dropped require no further action, and after 90 days the company is free to manufacture or import if it hears nothing from EPA. In order for the company to establish the substance on the TSCA inventory, it must submit a Notice of Commencement of Manufacture or Import within 30 days.

Key Metrics and Components

INCOMING NOTICES

The number of total PMNs and exemption requests received by OPPT has fluctuated from year to year but generally increased since the programs incept in 1979 up until 1995. In 1995 certain exemptions (primarily low volume and polymers) were expanded which have resulted in a decrease in the number of PMNs received. Current annual volume is approximately 2,000 submissions.

DISPOSITION BREAKDOWN

PMNs are dropped “along the way” during the review process for a variety of reasons. Only a small percentage make it to the standard review process and

very few are ever regulated or banned under section 6. Chronologically, the breakdown is typically as follows:

- Of 100 PMNs received, a small percentage (5-15%) may be dropped upon initial review at the Chemistry meeting. Reasons for dropping include substance is already on the TSCA inventory, is included in the polymer exemptions, or is not regulated by TSCA.

- Perhaps 80 PMNs will drop as a result of the Focus Meeting. Most (perhaps 80%) of these are dropped (or exemptions are granted), some (perhaps 10-15%) may be regulated under 5(e) consent order, and another 5% may require more research and continue through standard review.

- Only 5 PMNs reach the Standard Review process, and only very rarely will an item be banned as a result of the Standard Review.

PROCESSING TIME

Unless more time for review is required, the statute requires that PMNs are disposed of within 90 days. The breakdown of time is illustrated in figure 3-2. There is no backlog. PMNs are immediately introduced into the process following document control.

CBIC PROCESSING

The entire CBI process can take anywhere from 1 day to more than 5 days. Normal processing time is 2 to 3 days, however.

DATA PROCESSING

It takes approximate 5 minutes or less to enter the management data into CBITS. A large number and variety of other programs are used within each functional area to aid in analysis and report generation, and it is difficult to estimate the total effort required for entry into these programs.

INFORMATION SYSTEMS

There is no single information system that serves as the repository for the entire set of PMN data. Management data (less than 10 data elements) are entered into the Confidential Business Information Tracking System (CBITS) at the CBIC. Within each functional area or sub-process select data from the PMN may be entered into various stand-alone models and shared databases for analysis and historical tracking. Not all of the sub processes actually use the PMN as data input but may use outputs from other functional areas. For example, the Dose Response Assessment function rarely consults the actual PMN. Functional area inputs, analytical tools, and outputs are summarized in table 3-1 below:

Table 3-1 PMN Process Review Summary

Functional Area (subprocess)	Process Inputs	Tools and Data Stores	Process Outputs
Chemistry Assessment	PMN, TSCA Database, Beilstein Database	Stand-alone databases, Chembase, ISIS	Initial Review Chemistry Report (IRCR), et al
Production/Process Control	PMN, IRCR	Stand-alone, "Use" database	Initial Review Engineering Report, et al
Hazard Assessment	PMN, IRE/FR, IRCR, CSRAD	QSAR, various stand-alone Chembase modeling tools, PMN database,	Standard Review Hazard Assessment Report
Dose Response Assessment	CSRAD	Q1STAR stand-alone	Dose Response Assessment Report
Exposure Assessment	PMN, various paper stores	PC GEMS, SIDS, other stand-alone systems	Initial Review Exposure Report (IRER), Initial Review Exposure/Fate Report (IRE/FR), Pollution Prevention Plan
Risk Assessment	Standard Review Hazard Assessment Report, Dose Response Assessment Report	PMN Ecotox, Q1STAR, Submitter Test Results Database	Standard Review Risk Assessment Report, Test Data Risk Review, New Chemicals Exposure Limits
Economic Assessment	IRCR, IRER, Standard Review Chemistry Assessment Report	PIP Database	Standard Review Economic Assessment Report
Risk Management	Various Reports, MITS	Signed 5(e) Consent Order DB	Adverse Human/Environmental Outcome Report

DOWNSTREAM USES OF PMN DATA

Data from the PMN form are used to drive various automated analytical models and update historical databases in order to keep current the "pool" of knowledge about chemicals or families of chemicals. Data are entered into the databases by

individuals from the various functional areas. Databases updated and data elements are depicted in the Table below:

Table 3-2. Downstream Uses of PMN Data

Database Name	Platform or Program	Responsible Functional Area
Various: Lung, Gastrointestinal, Metabolism, Dermal	PC (Chembase)	Hazard Assessment
PMN Database	PC (Chembase)	Hazard Assessment
PMN Ecotox	PC (dBase II)	Hazard Assessment
PMN Chemical Class	PC (dBase II)	Hazard Assessment
HERD's Assessment of CERCLA reportable quantity (RQ) chemicals	PC (dBase)	Hazard Assessment
8(e) FYI Analogue	PC (Chembase)	Hazard Assessment
Q1STAR	PC (dBase III)	Dose Response Assessment
IRIS2	PC (stand-alone)	Dose Response Assessment
Select Industrial Dischargers System (SIDS)	PC (stand-alone)	Exposure Assessment
PC GEMS	FORTRAN	Exposure Assessment
Q1STAR	PC (dBase III)	Risk Assessment
Submitter Test Results	PC	Risk Assessment
PMN Ecotox	PC (dBase II)	Risk Assessment
PMN Information Program (PIP)	PC (dBase)	Economic Assessment
Submitter Test Results	PC	Risk Mgt/Regulatory Control
Signed 5(e) Consent Order DB	PC (Foxpro)	Risk Mgt/Regulatory Control

The PMN itself is sometimes used during the TSCA 12(b) Export Notice process. The PMN may be provided as an enclosure along with the Export Notice letter sent to the country of import and/or its embassy in Washington, D. C.

Deficiencies in the Process

Based on current processing we make the following observations:

- Data that are keyed (or typed) by the manufacturer or importer must be rekeyed into the various models and databases.

- Electronic access to and storage of PMN data is fragmented. Some data are entered redundantly, and other data are not entered at all.
- The CBIC process can be a significant part of PMN processing, both in time and effort.
- The process is paper and labor-intensive. The additional copies generated in the CBI process represent significant potential for lost documents. Documents are lost on occasion and significant effort is required to locate them.
- Manufacturers and importers must wait the full 90 days before production or import despite the fact that the PMN may have been dropped less than three weeks into the process.

Chapter 4 Chapter 4
Overview of Reengineering TSCA

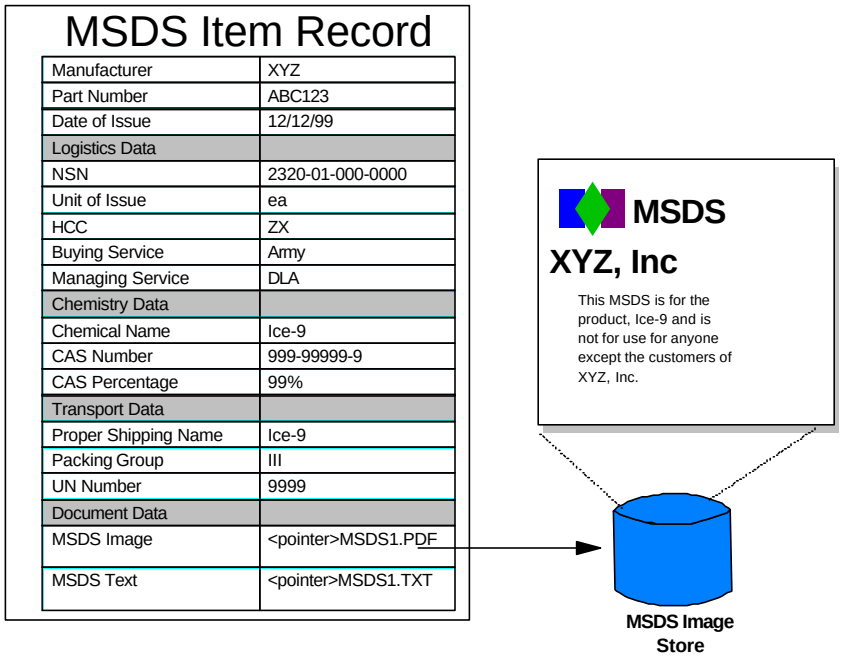
One primary theme emerges from reviewing both the existing information architecture and the comments made at the TSCA Reengineering Brainstorming Session; everyone involved with TSCA data (manufacturers, EPA personnel, the public) need quicker and greater access to the information. This connotes making the information available electronically beginning with the source of the data, the TSCA submitter, and propagating it through the process in a manner that is useful for all parties involved.

Given that TSCA submissions are business documents (and not transactions such as purchase orders, invoices, etc.), it follows that electronic document management and workflow are the tools most relevant to reengineering these processes. Technologies addressing these disciplines are strong at making processing more efficient by eliminating data entry and reducing the time to document access, enabling parallel rather than serial processing through simultaneous access to the data, and providing management a better view of the process.

At the time of TSCA's incept electronically stored data was managed in a proprietary, mainframe-style database format, and later, on a stand-alone PC. Capturing data in these databases required data entry read from paper forms. Advances in technology since then have resulted in applications which combine the benefits of pure database management, used primarily for transaction processing and advanced query capability, with the functionality of a document repository, the primary store of business data and records. The nature and use of most TSCA information suggest that current document repository technology can meet the users' requirements more effectively and efficiently than the existing databases that, in some cases, have proliferated throughout OPPT.

For the purposes of this discussion, it is useful to describe the basic mechanics of the document repository approach to data management. A document connotes a business object, which is used for reference or archived as a historical record. In contrast to a database record, it is generally static and enduring in nature. It is less likely to be used as the input to other applications or transactions. In strict terms, however, a document repository *is* a database. Users need to find and use certain elements of the documents. These elements are then fielded for retrieval or propagation purposes. Additional information, or "value," can then be provided as needed. The sum of the fields necessary for retrieval, propagation, and further classification result in the document repository structure. The document itself is usually stored as a link to an external object. In colloquial terms, the document record can be thought of as a "box" into which certain items are "thrown," including the TSCA submission itself, in the form of a link to an image of the submitted PMN, Health and Safety Study, or other object. A functional view of this approach is illustrated in Figure 4-2.

Figure 4-2. Example Data Structure



One reason it is useful to view the document repository in this way is because it then becomes easy to envision different individuals, or organizations, accessing and processing different areas of the record at the same time. Connected via a network, including the Internet, geographically dispersed activities can work in a parallel rather than in a serial and time-consuming, process. In addition, managing the submission as a document, and preserving the original submission through imaging, eliminates the need to reenter the entire document. In addition to the obvious efficiency gained from eliminating data entry, this improvement also serves as the legal record of submission without having to maintain a hard copy.

LMI

TSCA BPR Brainstorming Session

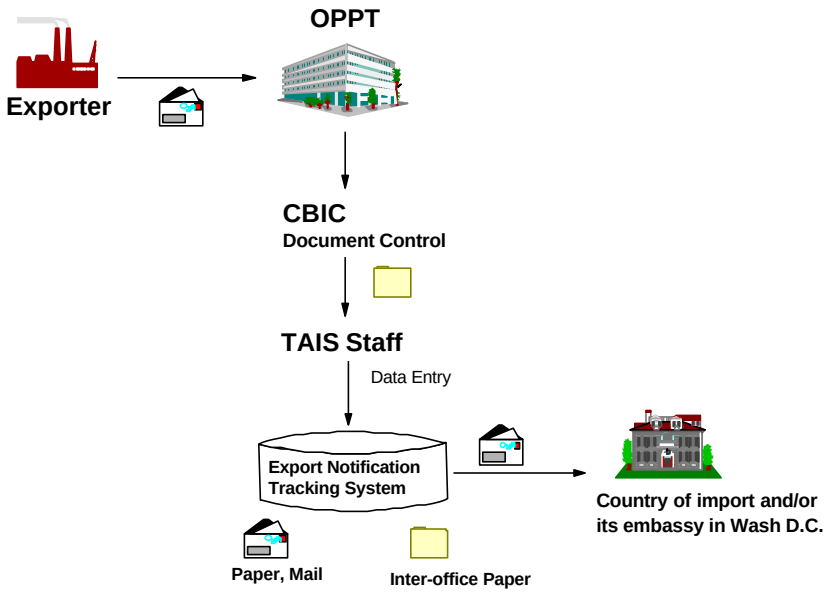
December 16, 1997

Logistics Management Institute
2000 Corporate Ridge
McLean, VA 22102
703 917-9800

Purpose and Conduct of Meeting

- **Share ideas about process improvement by unconstrained "brainstorming"**
- **Review process baseline, objectives, customers, and deficiencies**
- **Open discussion**
- **Use ideas to develop a theoretical, ideal process**

Export Notice



Export Notice: Process Objective and Customers

- **Primary Objective:**
  To alert and inform foreign countries of possible health and environmental hazards from chemical substances or mixtures that are subject to certain controls under TSCA.

- **Customers:**
  - **Countries of import**
  - **OECA for enforcement data/action**

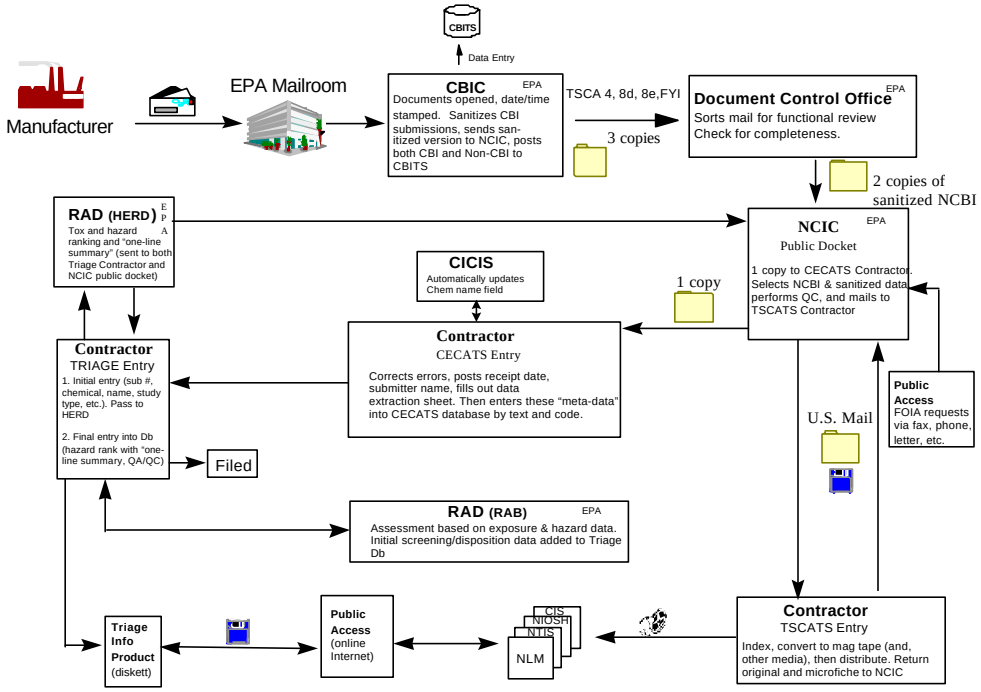
Export Notice: Process Deficiencies

- **Process often takes longer than 5 days as required by law, primarily due to processing at CBIC (even though most are NCBI)**
- **Data typed in by exporter must be rekeyed in at the TAIS Center.**

Ideas?

- Automate the distribution process of data (process lists)
- Automate workflow within OPPT (minimize manual intervention)
- Archiving schema for electronic files

Health & Safety Baseline



Health & Safety: Process Objective and Customers

- **Primary Objective:**

  Assess the potential for harm to humans and the environment from existing chemicals that are manufactured, processed or imported into the U.S.

- **Customers:**
  - **RAD scientists**
  - **Public**
    - NCIC
    - NLM, NTIS, NIOSH, etc.

Health & Safety: Process Deficiencies

- **The dbs for data management are incompatible because of dissimilarities**
- **Some data are not available to the public because of system incompatibilities**
- **Data that are keyed by the company must be rekeyed into multiple applications**

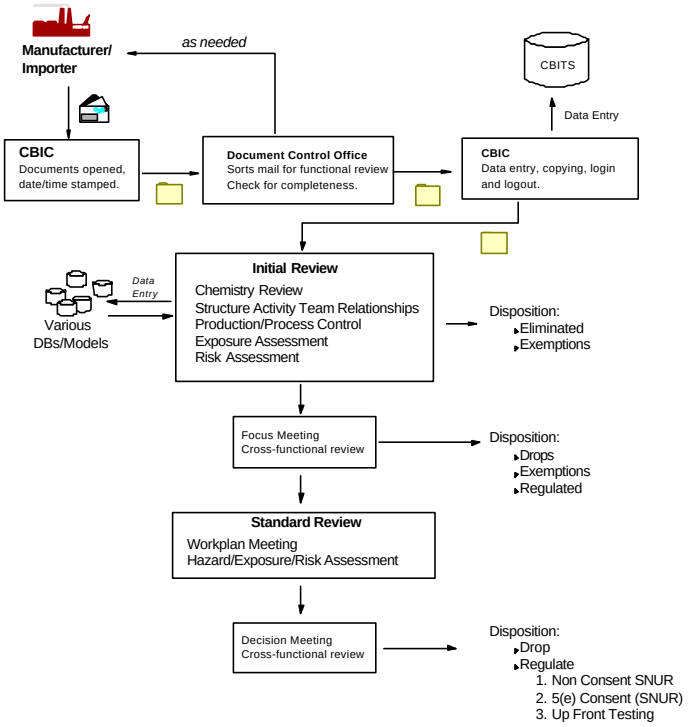
Health & Safety: Process Deficiencies, cont'd

- **Electronic access to and storage of Health and Safety data is redundant and fragmented**
- **Analysis and processing of Health and Safety data is redundant and fragmented**
- **The process is paper and labor-intensive**
- **Over 1 year's backlog of Health and Safety submissions is queued awaiting TSCATS input**

Ideas?

- Integrate data w/in all affected Dbs starting at CBITS (emphasize QA/QC)
- CBIC should have highest level of QA/QC
- Enter data once, perpetuate throughout
- Distribution of data to both analysts and public
- Cover sheet from industry (non-CBI) available quickly
- Automated data sharing between systems
- Access to CBITS data?
- Links from CBITS to an integrated Db
- Entry of paper into the system - where?
- When and how does industry get the DCN/bar code?
- Cover Sheet/study link

PMN Baseline



PMN: Process Objective and Customers

- **Primary Objective:**

  Protect public and environmental health by ensuring that new substances are not produced or imported in mass quantities until the risks associated with that substance are better understood, and, if necessary, to regulate production or import of that substance to prevent unnecessary risk to health and environment.

PMN: Process Objective and Customers, cont'd

- **Customers:**
  - ⇨ **Manufacturers and importers**
  - ⇨ **Subject matter experts (SME's) within OPPT**
  - ⇨ **Countries of export (under TSCA 12b)**

PMN: Process Deficiencies

- **Electronic access to and storage of PMN data is all at once redundant, fragmented, and non existent**
- **Manufacturers and importers must wait the full 90 days before production or import**
- **Data that are keyed by the company must be rekeyed into multiple applications**

Ideas?

- Electronic PMN form w/all required data elements
- Make those data available to all who need them
- Enter data once, perpetuate throughout
- Easy access to archived data, decisions, logic, etc.
- Integrated data
- Electronic record housekeeping per policy
- Efficient upgrading of incorrect source data (both before and after data has populated the integrated Db)
- Automated workflow and notification capability
- Links to different views of data
- Molecular structure/sub-structure search capability
- Electronic ack to Mfgr (encripted E-mail?)
- Paper integration within the electronic process
- Standardized PMN test data
- Perpetuation of value-added data throughout process flow

Ideas?

- Concurrent review of Access and Decision letters